UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	)	Judge Patti B. Saris
	)	Chief Magistrate Judge Marianne B. Bowler

PLAINTIFFS' REPLY TO SCHERING-PLOUGH GROUP'S INDIVIDUAL MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION

[REDACTED VERSION]

I. INTRODUCTION

In opposing certification of claims involving generic drug purchases, Defendants essentially recycle the same arguments previously raised and rejected by this Court in the motion to dismiss phase, namely, that it is impossible for generic manufacturers to compete on the basis of AWP spreads because the generic reimbursement methodology relies on median AWPs (in the Medicare Part B world) and MAC prices (in the private payor world) and, thus, a single manufacturer's AWP could not have defrauded Plaintiffs. *See* Schering-Plough ("SP") Br. at 1-2;[1] Track 1 Defendants' Memorandum in Opposition to Class Certification ("Defs. Br.") at 49. Yet, the scheme in the generic market is very similar to that perpetrated for brand name drugs because (i) generic manufacturers establish their AWPs (*see* AMCC ¶¶ 185-87; *see also* Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification ("Hartman Decl."), Attach. E, ¶ 16); (ii) private and public payors reimburse based on methodologies rooted in the AWP system, either directly or by virtue of AWP medians or MACs that incorporate AWPs (*see* AMCC ¶¶ 181-84); (iii) generic AWPs were inflated, often at a much higher rate than brand name drugs (*see* AMCC ¶ 187); and (iv) generic manufacturers benefit from AWP inflation (*see* AMCC ¶ 187).

Indeed, on the same day of the tutorial where Defendants were claiming generic drugs and AWP had no relation, the CFO of generic manufacturer Dey testified before Congress that "the current system is based on AWP and customers rely on it and won't buy product without it." She further admitted that manufacturers maintain the AWP, while the actual selling price is getting lower (*i.e.*, spread is increasing), with "money realized from the spread going to providers."[2] Her statements parallel the scheme alleged in this case. Consequently, Plaintiffs have suffered a compensable loss because a scheme that inflates AWPs will ***necessarily and***

[1] As the Court is likely already aware, all of Schering-Plough's citations to Young's declaration are inaccurate in that the paragraph numbers cited in the brief fail to correspond with the appropriate paragraphs of Young's declaration. In some cases, Plaintiffs could not locate support for the proposition cited in Young's declaration at all.

[2] Ex. 1 (Statement of Pamela Marrs before House Subcommittee, December 7, 2004). Unless otherwise indicated, all exhibits referenced in this reply memorandum are attached to the Declaration of Steve W. Berman in Support of Pltfs.' Reply Mem. to SP's Individual Mem. in Opp. to Class Certification.

foreseeably inflate median AWPs and the MAC prices that are ultimately paid by Class members for generic drugs. Common issues predominate with respect to generics, and Plaintiffs' claims involving generic drugs should also be certified as class claims.

II. ARGUMENT

A. AWP Inflation Occurs in the Generic Drug Market.

The AMCC is replete with examples of inflated spreads for generic drugs and evidence that generic manufacturers directly compete based on AWP spreads. *See, e.g.,* AMCC ¶¶ 278-80 (where Baxter, after acknowledging the existence of "deliberate manipulation of AWP" as a method to "increase product positioning," then "adjusted our AWPs to meet competitive levels"); AMCC ¶ 291 (Bayer increasing AWP on generic drugs to meet competition); AMCC ¶¶ 318-20 (B. Braun, after acknowledging that the practice was "scandalous, or worse, fraudulent," then evaluated its AWPs against Baxter's and Abbott's, and increased them to "make them equivalent."). Indeed, generics have some of the highest spreads of any drugs. AMCC ¶ 187; *see also* 68 Fed. Reg. 50,428 (August 20, 2003) ("In general the 'spread,' in percentage terms, is larger for the generic drugs examined in the studies than for brand drugs."). The rationale for this is simple: under circumstances where biological or therapeutic equivalents are acknowledged to exist, competition on price is most fierce because of lack of therapeutic differentiation. Hartman Decl., ¶ 19. As a result, generic drug makers are "able to push market share for their generic products by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain." AMCC ¶ 183.

Dr. Hartman has confirmed that price manipulation occurs in the generic sphere:

> [M]arket events demonstrate that as generics have launched, generic manufacturer prices (ASPs) have fallen 80-90% below pre-generic brand-name drug prices, while reimbursement rates paid to retailers (by TPPs and PBMs) have fallen by only 20-30%. Hence, it would appear that generic reimbursement rates paid at retail do not adequately reflect the aggressive price reductions offered at wholesale by manufacturers.

Hartman Decl., ¶ 19(c), p. 16-17; *see also* Hartman Attach. E, ¶ 18 (describing how the data demonstrate spread increases for generics). Indeed, Dr. Hartman has confirmed average spreads

on generic Schering drugs of as high as 3,878%, with most of the average spreads in the triple digits. Hartman Decl., Table 2.C.

Dr. Hartman's observation is consistent with Schering/Warrick's own description of the manner in which it establishes AWPs for its generic drugs: "Generally, Warrick has reported AWP upon the launch of its products at 10%-20% below the equivalent brand product's AWP, and that reported AWP has generally remained constant over time" even though actual prices frequently change. Wein. Decl., ¶¶ 11-12; SP Br. at 4-5. In other words, Schering's generic AWPs do not reflect, and are never adjusted to reflect, the 80-90% decrease in ASP that occurs when generics enter the market – as observed by Dr. Hartman. Rather than adjust AWP in accordance with price adjustments, "Warrick has simply suggested an AWP at launch and has, in almost all instances, left it untouched for the life of the product." Wein. Decl., ¶ 13. Thus, Warrick validates Dr. Hartman's conclusion that Class members have been injured and overcharged for generic drugs on a common basis. "To the extent that Class members reimburse at rates reduced by only 20-30%; that retailers acquire the generics at ASPs discounted by 80-90%; and that AWP should be a reasonable signal for ASP/AAC; those End-Payer Class members were injured and overcharged." Hartman Decl., ¶ 19(c).

B. Reimbursement of Generic Drugs at a Median AWP is Not a Bar to Certifying a Class of Medicare Part B Co-payers.

Generics are reimbursed under Medicare Part B at "the less[er] of the median AWP of all of the generic forms of the drug or biological, or the lowest brand name product." 42 C.F.R. § 405.517; *see also* AMCC ¶ 184. Defendants argue that "reliance on a median AWP destroys any linkage between any individual defendant's reported AWP and a payor's price for a prescription drug," SP Br. at 7 (citing Gaier Decl., ¶ 67) and 9, and that a manufacturer cannot gain a competitive advantage by inflating its AWP for generic drugs because a single manufacturer cannot control the median AWP. SP Br. at 8-10 (citing Young Decl., ¶ 197). Defendants' argument is illogical and contradicts the many documents cited in the AMCC that

reveal egregious AWP spreads and competition amongst generic manufacturers based on AWP spreads.

As a matter of simple mathematics, if multiple manufacturers are reporting inflated AWPs, the median of course goes up – ***especially where there are only a limited number of manufacturers selling a particular generic drug*** (the fewer the alternatives, the greater the ability of one manufacturer to affect the median). Indeed, in a report on the impact of high-priced generic drugs on the Medicare and Medicaid programs, HHS concluded that "***high-priced generic drugs have a significant financial impact on Medicare … reimbursement***" because, even though a median calculation is used, "[h]igher-priced generic drugs will still be included in the median calculation."[3] Among other drugs, HHS reviewed reimbursements for vancomycin and etoposide – generic drugs that had few manufacturers – and actually found AWPs that were higher than the brand name drug. *Id*. at i.[4]

Thus, it is clear that inflating AWPs for generic drugs inflates Medicare reimbursement and therefore Medicare co-pays. On a drug-by-drug basis, Plaintiffs' experts will be able to model the impact that AWP inflation had on the median.

C. A Scheme to Inflate AWPs Necessarily Impacts Private Payor Reimbursement of Generic Drugs Because Such Reimbursement is Tied to AWPs.

Private payors who reimburse for generics outside of the Medicare Part B context are also injured where reimbursement is tied to inflated AWPs. As evidenced by expert testimony on both sides and the testimony of putative Class members, generic reimbursement is either based on AWP directly or on MAC, which is almost always a function of AWP. In the latter instance, the fact that various formulae may be used to calculate MAC is not a bar to class certification; despite individual formulas, the fact remains that MACs derived from inflated AWPs caused Plaintiffs to overpay, making class-wide impact susceptible to common proof.

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[3] *The Impact of High Priced Generic Drugs on Medicare and Medicaid, Draft Report*, Ex. 2 at ii (emphasis added).

[4] Prior to January 1, 1998, the Medicare reimbursement formula was purely based on the median AWP of the generics and did not consider whether the brand name AWP was lower. *Id.*

1. Many generic drug reimbursements are based on AWP, not MAC.

It must first be noted that ***not all private payor reimbursement of generic drugs is tied to MAC, as some purchases are reimbursed using the straight AWP benchmark***. *See* Hartman Decl., Attach. E, ¶ 16. As Dr. Rosenthal summarized: "When a generic version of a drug first becomes available, reimbursement is based on a discount off of AWP, just like brand name drugs. When there are multiple generics on the market, PBMs will reimburse (and charge third-party payors) based on the lesser of AWP less a discount, the usual and customary charge of the pharmacy, or the Maximum Allowable Cost (MAC)." Rosenthal Tutorial at 19.[5] Importantly, "[d]ue to the recordkeeping in the industry we can identify those health plan payments for generic drugs that are expressly based on AWP." *Id.* For example, Dr. Rosenthal examined the claims data for Harvard Pilgrim Health Care ("HPHC") in this case and was able to conclude that 53% of HPHC's generic purchases were based directly on AWP, not MAC. *Id.*; *see also* App. 1(f); Ex. 3 [redacted]; Ex. 4 [redacted]. Even Defendants' expert, Young, agrees that at least some generic transactions are reimbursed at AWP. *See* Young Decl., Ex. 17d (establishing that a portion of CIGNA's generic drug reimbursement is based on the straight AWP benchmark, not MAC). Such generic purchases are clearly based on AWP, and Defendants have no argument that such generic purchases should be stricken from the Class.

2. The claims data supports class-wide use of AWP for generic drugs.

By definition, the Class includes only payors whose contracts use AWP in the reimbursement formula, including for generic drugs.[6] Dr. Hatman's analysis and Dr. Rosenthal's

[5] Furthermore, all four of the major PBMs (Caremark, AdvancePCS, Medco and Express Scripts) charge for non-MAC qualifying generics at a discount off of AWP. Rosenthal Tutorial, Ex. 20. In addition, in at least some contracts, Medco charges AWP less a percent for generics sold through their mail order facility without any reference to MAC. *Id.*; *see also*, *e.g.*, Ex. 5 [redacted]; App. 1(g) (all references to "App." are to appendices compiled in Plaintiffs Appendix of Summary Charts in Support of Class Certification) and Ex. 6 [redacted]

[6] As Schering notes, the Class definition does not reference MAC, but this does not in any way complicate certification of generic drug claims because contracts that reference MAC also reference AWP in some way.

tutorial demonstrate that the AWP is expressly used in contracts as the pricing standard for generic drug reimbursement for the first generic launched. Dr. Hartman's claims data analysis demonstrates that AWP is a reference point for generic drug reimbursements in the following ways: (i) such transactions are readily identifiable; (ii) the reimbursement claims for the first generic(s) launched track closely with and generally as a fixed percentage off AWP; and (iii) as more generics come to market and the reimbursement rates go to MAC, the reimbursement rates paid trend below AWP in an observable and predictable fashion.[7] Indeed, using proper analytical techniques, as well as relying on academic studies specific to generic drugs, Dr. Hartman explains why generics are tied to AWP.[8]

3. The Class encompasses reimbursements based on MAC because MACs are directly tied to AWPs.

Schering's contention that MAC prices "have little or no relationship to AWP," *see* SP Br. at 5, is flat out wrong. [redacted][9] *See, e.g.*, Ex. 9 Ex. 13 [redacted]

[7] Hartman Rebuttal Decl., ¶ 27.

[8] Hartman Rebuttal Decl., ¶ 32(d), ¶ 33(b), and Attachment D.2, showing typical pattern of generic pricing and the increasing spread over time.

[9] *See* App. 1(g) (containing deposition excerpts evidencing that MAC is based in part on AWP); Ex. 7 ([redacted] Ex. 8 Ex. 9 Ex. 10 Ex. 11 Ex. 12 [redacted]

[redacted] *See* Ex. 4 ; *see also* Ex. 3 Ex. 14 Ex. 11 [redacted]

Plaintiffs' experts have confirmed that MACs are indeed tied to AWPs. *See* Ex. 15 [redacted] and 508-09 *see also* Ex. 16 [redacted]; Rosenthal Tutorial at 19 n.44 ("To stabilize the cost variance of different generic products of the same compound, pharmacy benefit administrators calculate [MAC] based upon the listed average wholesale prices of competing generic drug manufacturers").

Defendants' experts do not, and cannot, contradict the fact that AWP plays a role in creation of MACs. They only assert that MAC prices are arrived at in a variety of ways. SP Br. at 6 (citing Young Decl., ¶ 185); *see also* Young Decl., ¶ 191; Gaier Decl., ¶ 68.[10,11]

[10] Notably, Schering must revert to citations taken out of context and misrepresentation of the evidence. For example, Schering misrepresents Dr. Hartman's testimony when stating that "Plaintiff's own experts now confirm that there is no evidence that MAC prices are set by reference to AWP." SP Br. at 5-6. For support, Schering points to Dr. Hartman's statement that "how TPPs actually define MAC and the extent to which the TPPs strictly enforce MAC are unknown." *See* SP Br. at 5-6 (citing Hartman Decl., Attach. D, ¶ 37). By its plain language, the statement does not even resemble the proposition cited by Defendants. In fact, in the same paragraph, Dr. Hartman describes an example of a MAC calculation based on AWP. *See id.* at ¶ 37, n. 60. Defendants similarly misinterpret an excerpt from a PBM response to a Request For Proposal by suggesting that the following statement stands for the proposition that MACs are not related to AWP: "the MAC will replace [AWP] for the selected drugs in determining the ingredient cost, without regard to the drug's published AWP." *See* SP Br. at 6 (citing Young Report, ¶ 190). It simply does not follow that MACs are unrelated to AWP; the statement merely conveys that MAC does not equate to AWP in that particular case.

[11] Ignoring these direct reimbursement ties to AWP, Defendants invoke the Hatch-Waxman Act, the 6-month exclusivity period for the first generic on the market, the fungible nature of generic drugs and an "auto-substitution" program operated by some wholesalers and distributors. SP Br. at 3-5, 8. But these irrelevant matters add nothing to the analysis, as generic reimbursement remains tied to AWP, and AWP spreads persist in the generic marketplace.

Furthermore, Dr. Hartman will use common proof to demonstrate the impact of AWP inflation on payors who reimburse based on MAC. He has determined that the relationship between MACs and AWP prices is consistent, predictable and capable of measurement. By analyzing claims data comparing MAC prices with AWP prices for generic drugs in Attachment D.2 and generic drugs more generally, Dr. Hartman concludes that MAC prices fall to an average discount off AWP of approximately 30-40% generally and for the specific drugs and specific payors in his Attachment D.2 MAC prices fall to an average discount off AWP of 25-40%.[12] *See* Hartman Rebuttal Decl., ¶ 33.b and Attachment D.2; *see also* Ex. 15 [redacted] and 516-24 [redacted]. While methodologies might vary as to how AWP is factored into the MAC equation, Dr. Hartman's findings make clear that the relationship between MAC and AWP is consistent and predictable. Thus, using his "but for" methodology, Dr. Hartman is able to determine what the MAC price should have been if unaffected by the fraudulent pricing scheme and thereby calculate aggregate damages to the Class. *See* Hartman Decl., ¶¶ 20-25; Ex. 15 [redacted]

Importantly, this analysis suffices, as "Plaintiffs do not need to supply a precise damage formula at the certification stage …. Instead, in assessing whether to certify a class, the Court's inquiry is limited to whether or not the proposed methods are so insubstantial as to amount to no method at all." *See In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672, 698 (S.D. Fla. 2004) (citations omitted). Plaintiffs need only come forward with "plausible statistical or economic methodologies to demonstrate impact on a class-wide basis." *Id.* at 698. As such, this Court need not examine individual methodologies for determining MAC and need not make a case-by-case review of all transactions involving MAC in Phase I. Individual damages, based on variations in MAC, can be determined during Phase II, as is typical in class actions. *See* Ex. 15

[12] The specific drugs are clotrimazole, griseofulvin and potassium chloride (K-Dur); the specific payors are HPHC, HIP of New York and BCBS of Kansas City. The discount on clotrimazole to HPHC for several years was greater than 40%.

[redacted].

The fact that MAC methodologies might vary does not render individual issues predominant over common ones. The variation in MAC formulas is essentially a question of varying damages to individual Class members, and "[t]he individuation of damages in consumer class actions is rarely determinative under Rule 23(b)(3)." *Smilow v. Southwestern Bell Mobile Sys.*, 323 F.3d 32, 40 (1st Cir. 2003); *Wachtel v. Guardian Life Ins. Co.*, 223 F.R.D. 196, 214 (D.N.J. 2004) (certifying a class of health plan beneficiaries despite the fact that one subject of the lawsuit – payment of Usual Customary and Reasonable ("UCR") charges – were subject to varying contractual definitions, noting "[d]amages can be addressed after liability is determined on a classwide basis."). Once the damages phase is reached, it is unlikely that issues will prove to be unusually or especially complex because Dr. Hartman's analysis suggests that MAC prices tend to be a consistent level below AWPs despite the use of different MAC formulas.

D. Defendant Dey Confirms the Common Impact of the AWP Inflation Scheme In the Market For Generic Drugs.

It is important to drive home a final point: perhaps no one "makes the case" for the importance of creating and promoting "spreads" on generic drugs – and the resulting common and adverse impact on Class members – better than does Defendant Dey, Inc. In a lawsuit brought by Dey against two Publishers (*First DataBank* and *Medi-Span*) for purportedly publishing independently-derived AWPs for Dey generics instead of those reported by Dey, Dey acknowledged that private payors utilize AWP in their reimbursements for generic drugs. AMCC ¶ 189(c) (citing ¶ 13 of Dey Complaint). Moreover, Dey admitted that generic manufacturers are "cognizant of, and are highly attentive to, AWPs as reported … because of the ***direct relationship*** between the level of reimbursement … and the reported AWPs of these drugs." AMCC ¶ 189(e) (quoting ¶ 38 of Dey Complaint) (emphasis added). A reasonable inference of the word "attentive to" in this context is that it refers to "competition." And

contrary to Defendants' argument that generic manufacturers do not inflate AWPs, Dey admits the exact opposite and confesses that competition on this basis occurs:

> Since reimbursement to Dey's customers is, in Medicaid program in many states ***and in and [sic] insurance programs***, most frequently based on the AWP as reported by the reporting services, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP would result in a drastic reduction in the reimbursement to drug providers who choose to dispense Dey's product. ***Since there has not been a comparable reduction in the AWP for Dey's competitors***, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive.
>
> ***Because reimbursement for Dey products would be significantly reduced, but reimbursement for those competing products would remain as they have been, Dey is prevented, by First DataBank's and Medi-Span's arbitrary and capricious acts, from effectively competing in the marketplace***.

AMCC ¶ 189(e) (quoting ¶¶ 50-54 of Dey Complaint) (emphasis added).

Dey is thus admitting that without the use of inflated AWPs, like those of its competitors, it cannot compete; indeed, "within one day" of the truth being revealed that AWPs were not as inflated as Dey was reporting, Dey was losing customers. In recent testimony before a House subcommittee, Dey's CFO admitted that the "spread is still meaningful to providers," and "[i]f the spread for a particular Dey drug is getting larger, it is almost always because the AWP of the drug is remaining the same, while the actual selling price is getting lower."[13] And she confirmed that with respect to generic drugs, "the current system is based on AWP and customers rely on it.…" *Id*. at 3. Dey's admissions utterly belie the assertions made by all generic manufacturers that there is no economic reason to inflate AWPs on multiple source drugs. Defendants have now had several opportunities to at least ***attempt*** to explain away the salient significance of the Dey suit but have thus far failed to even acknowledge its existence. This omission rings loudly.

III. CONCLUSION

For the reasons set forth above and in Plaintiffs' opening brief, the Court should certify Class claims involving generic drugs.

[13] Ex. 1 at 3.

DATED: December 17, 2004.

By **/s/ Steve W. Berman**

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CERTIFICATE OF SERVICE

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing, **PLAINTIFFS' REPLY TO SCHERING-PLOUGH GROUP'S INDIVIDUAL MEMORANDUM IN OPPOSITION TO CLASS CERTIFICATION** to be electronically filed with the Court pursuant to the December 16, 2004 Order and to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on December 17, 2004, a copy to Verilaw Technologies for Posting and notification to all parties

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